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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MAKI, STEVEN D	

ART UNIT	PAPER NUMBER
1733	

DATE MAILED: 04/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/053,102	FOX ET AL.	
	Examiner	Art Unit	
	Steven D. Maki	1733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-42* is/are pending in the application.

4a) Of the above claim(s) *40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-39,41 and 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1) Newly submitted claim 40 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

This application contains claims directed to the following patentably distinct species of the claimed invention:

species #1 (originally claimed invention): process for producing a medical test implement including sealing with a thermosensitive adhesive (original claims 16-18);

species #2 (new claim 40) method for manufacturing a plurality of medical test implements including mechanically bonding, described for example at page 14 lines 1-7 of the original specification.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 19-35, 41-42 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 40 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2) The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "62" and "66" have both been used to designate the end of sheet 10. It is suggested to change "62" in figure 8 to --66--. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

The drawing correction for figure 8 filed 12-22-03 has not been approved because the proposed figure 8 uses "62" and "66" to designate the ends of sheet 10 whereas original figure 7 uses "62" to designate a score line and "64" and "66" to designate the ends of the sheet 10.

3) The disclosure is objected to because of the following informalities: In the replacement paragraph filed 12-22-03 for the paragraph starting at page 8 line 10, "ends

62, 66" should be --ends 64, 66--. Also, the specification does not describe "18" and "48" indicated in figure 5.

Appropriate correction is required.

4) The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5) Claims 41 and 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claims 41 and 42, the subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (i.e. the new matter) is the *omission* of the subject matter of the ability of the test element to deform when a predetermined load is applied thereto. The original disclosure fails to reasonably convey the *omission* of the subject matter of the ability of the test element to deform when a predetermined load is applied thereto since (1) the original disclosure teaches that the medical test element must have the ability to deform when predetermined load is applied thereto in order to function as a LEAP Testing Implement and (2) the original disclosure fails to disclose a medical test device having a test element, which cannot deform when a predetermined load is applied thereto.

6) The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7) Claim 36 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 36, there is no antecedent basis for "the handle forming member". Should "handle forming member" be "handle forming material"?

8) The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9) Claims 19-20, 26-34, 36 and 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Footscreening (including "Making LEAP Filaments" / supplied by applicant) in view of Schwobel et al (US 6207000) and optionally at least one of Mohr (US 3616083), Lindley (US 3511735) and Winesett (US 2469536).

Foot Screening includes "Making LEAP Filaments: Instructions for Camera Art Work". See pages 34 and 35 of Footscreening. "Making LEAP Filaments" discloses making a medical test implement (a LEAP testing implement) by:

providing a sheet such as index card stock,

providing a 5.07/10gm nylon filament;

printing on the sheet;

applying adhesive to the sheet;

perforating (separating) the sheet along a line so as to defines two halves;

cutting the sheet to a size of 2 inches by 1 ¾ inches (50.8 mm to 44.5 mm);

folding the sheet along the perforated line such that the filament is bonded between the two portions of the sheet and extends a distance of 37-39 mm from an edge of the folded sheet. Since "Making LEAP Filaments" describes (1) "...tell us how many you plan on producing so we can send you the required number of filaments ..." (emphasis added), (2) "[t]his artwork should be sized as shown above and prepared for mass printing. We suggest producing *an array of each view* (front and back view) on standard 81/2 x 11 paper..." (emphasis added) and (3) "...cut the tabs into single components", "Making LEAP Filaments" teaches producing a plurality of medical test implements" using a plurality of filaments and a single sheet. "Making LEAP Filaments" does not specifically recite adhering the filaments between the portions of the folded sheet and **then** cutting the sheet to form a plurality of medical test implements.

As to claim 19, it would have been obvious to one of ordinary skill in the art to adhere the filaments between the portions of the folded sheet and **then** cut the sheet to form a plurality of test implements (bond and then cut to form plural individual products) since (1) "Making LEAP Filaments", directed to production of medical test implements for testing diabetics, teaches producing the medical test implements using a bonding step and a cutting step, (2) Schwobel et al, directed to production of medical test devices which may be used in self control of blood sugar by diabetics, suggests producing such medical test devices at low production cost and high production rate by bonding and **then** cutting individual medical test devices from the laminate and

optionally (2) it is well known / conventional in the bonding art to bond and **then** cut individual products in order to mass produce the products as evidenced by at least one of Mohr, Lindley and Winesett. In claim 19, the step of separating reads on the perforating step of Making LEAP Filaments. In claim 19, the step of mechanically mating reads on the bonding using adhesive as per the teachings of Making LEAP Filaments.

As to claim 20, Making LEAP Filaments suggests facilitating folding by perforating (scoring) the sheet.

As to claims 26-29, the claimed dimensions of the test element (corresponding to the filament) and the handle (made from the sheet) would have been obvious in view of (1) "Making LEAP Filaments" teaching to use the sheet and filament to make a device for Lower Extremity Amputation Protection and (2) the specific dimensions disclosed by "Making LEAP Filaments" for the cut sheet and the filament.

As to claims 30 and 31, note "Making LEAP Filaments" suggestion to use a sheet such as an index card (paperboard). As to claim 31, a plastic sheet is taken as well known / conventional per se); it being noted that the suggestion to use a sheet comes from "Making LEAP Filaments".

As to claims 32-34, note the nylon filament suggested by "Making LEAP Filaments".

As to claim 36, "Making LEAP Filaments" teaches applying adhesive to the sheet.

As to claims 41 and 42, it would have been obvious to obvious to one of ordinary skill in the art to use a continuous sheet of handle forming material so as to automate the process of Making LEAP Filaments since (1) Making LEAP Filaments suggests producing medical test implements for diabetics from sheet material, (2) Schwobel et al suggests using continuous sheet material to make medical test devices for diabetics at low cost and high production rates and optionally (3) it is well known in the bonding art to produce products, which like that of Making LEAP Filaments comprise a discrete article bonded to a sheet, from a continuous sheet in order to mass produce the products as evidenced by at least one of Mohr, Lindley and Winesett. Furthermore, it would have been obvious to provide the process of Making LEAP Filaments with the claimed machine for folding and separating and the claimed test element placement machine in view of (1) the teaching in Making LEAP Filaments that the process includes a folding step, a separating step (perforating step) and a test element placement step and (2) the suggestion from the secondary art (i.e. Schwobel et al and the optional at least one of Mohr, Lindley and Winesett) to automate the process of Making LEAP Filaments; it being noted that (a) Mohr teaches an "element placement machine" for placing elements on a continuous sheet and (b) Winesett teaches using a "suitable folding means" to fold continuous sheet material.

10) Claims 21 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Footscreening (including "Making LEAP Filaments" / supplied by applicant) in view of Schwobel et al and optionally at least one of Mohr, Lindley and Winesett as applied

above and further in view of McGill et al (Use of the Semmes-Weinsten 5.07/10 Gram Monofilament: the Long and the Short of it" / supplied by applicant).

As to claim 21, it would have been obvious to one of ordinary skill in the art to cut a nylon monofilament to the length for allowing it to protrude out of the folded sheet by 37-39 mm as described by "Making LEAP Filaments" since McGill et al, also directed to Lower Extremity Amputation Protection, teaches cutting a nylon filament to obtain a desired length for Lower Extremity Amputation Protection.

As to claim 35, the limitation therein would have been obvious in view of Footscreening's suggestion to inspect for bent filaments and the testing of filaments suggested by McGill et al.

11) Claims 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Footscreening (including "Making LEAP Filaments" / supplied by applicant) in view of Schwobel et al and McGill et al and optionally at least one of Mohr, Lindley and Winesett as applied above and further in view of Weihrauch (US 4807938).

As to claims 22-25, it would have been obvious to one of ordinary skill in the art to heat a continuous nylon filament before cutting the filament since (1) McGill et al, also directed to Lower Extremity Amputation Protection, emphasizes that (a) non-uniformity in filaments causes difficulties in applying a correct buckling force and (b) reliability of these filaments is essential and (2) it is known in the filament art to improve the uniformity of a filament by heating the filament to eliminate curvature and make the filament straight as evidenced for example by Weihrauch. The need for the filament to be straight is additionally suggested by the following statement in "Foot Screening-Care

of the Foot in Diabetes" : "Occasionally you will find a filament that seems to be abnormal (it may be thinner or it may be bent). Just discard that filament. A small bend in the filament will not distort the delivery of 10 grams of force. However, one that is really bent may. We suggest that you throw questionable filaments away". The claimed temperature and time would have been obvious and could have been determined without undue experimentation in view of Weihrauch's suggestion to heat a filament to straighten the filament.

12) Claims 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Footscreening (including "Making LEAP Filaments" / supplied by applicant) in view of Schwobel et al and optionally at least one of Mohr, Lindley and Winesett as applied above and further in view of Adhesives Technology Handbook.

As to claims 37-39, it would have been obvious to one of ordinary skill in the art to use a heat activated adhesive as the adhesive in Making LEAP Filaments and apply heat to cause bonding since (1) "Making LEAP filaments" suggests adhering the filament between the portions of the folded cut sheet using adhesive (adhesive tape) and (2) Adhesives Handbook teaches that known adhesive include heat activatable adhesive (for example heat activatable adhesive on tapes) wherein the assembly of parts to be bonded are heated and occasionally the parts are heated before the parts are mated.

As to claims 38 and 39, note the suggestion from Adhesives Handbook to use heat activatable coatings to bond parts together.

Remarks

13) Applicant's arguments with respect to claims 19-39, 41 and 42 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments filed 12-22-03 have been fully considered but they are not persuasive.

Applicant argues that Foot screen is specifically limited to forming a single test implement. Applicant is incorrect. Since "Making LEAP Filaments" describes (1) "...tell us how many you plan on producing so we can send you the required number of filaments ..." (emphasis added), (2) "[t]his artwork should be sized as shown above and prepared for mass printing. We suggest producing *an array of each view* (front and back view) on standard 81/2 x 11 paper..." (emphasis added) and (3) "...cut the tabs into single components", "Making LEAP Filaments" teaches producing a plurality of medical test implements" using a plurality of filaments and a single sheet.

Applicant argues that Schwobel, Lindley and Mohr are non-analogous art. The examiner disagrees. Schwobel is in the same field of endeavor (making a test device for diabetics) as Making Leap Filaments. Lindley and Mohr, like Making LEAP Filaments, are directed to the same problem of producing plural products wherein each product has an element bonded to sheet material. The motivation to make plural medical test devices is found in Making LEAP Filaments and Schwobel. The specific suggestion to make plural LEAP medical testing implements (instead of merely only one LEAP medical testing implements) is found in Making LEAP Filaments.

Applicant's arguments regarding Weihrauch are not persuasive since one of ordinary skill in the art having the teaching in McGill et al / Footscreenings that the filament for the LEAP medical testing implement must be straight would look to prior art such as Weihrauch which teaches how to obtain a straight filament.

14) No claim is allowed.

15) Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven D. Maki whose telephone number is (571) 272-1221. The examiner can normally be reached on Mon. - Fri. 7:30 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino can be reached on (571) 272-1226. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Steven D. Maki
April 5, 2004

Steven D. Maki 4-5-04
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